An observational cohort study to evaluate the risk of adverse pregnancy outcomes in patients treated with etanercept compared to those not treated with etanercept or other biologics using merged data from Sweden, Denmark and Finland

First published: 13/08/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20081

Study ID

25620

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Sweden

Study description

This is a population-based study of data from the national health registers of Sweden, Denmark and Finland. The study will compare the rate of adverse outcomes, including birth defects, preterm birth, small for gestational age and infections in infancy among infats to women exposed to etanercept with infants to women not exposed.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

- [ ] Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

Department of Clinical Epidemiology Aarhus University, Aarhus, Denmark, National Institute for Health and Welfare Helsinki, Finland

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Helle Kieler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2017

Actual: 01/07/2017

Study start date

Planned: 01/07/2006

Actual: 01/07/2006

Data analysis start date
Planned: 01/07/2017

Actual: 01/07/2017

Date of final study report
Planned: 31/12/2018

Actual: 02/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Enbrel PASS protocol_B1801396_v 3.pdf (1.05 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To compare the risk of adverse birth outcomes in women exposed to etanercept during pregnancy to those not exposed.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Rheumatoid arthritis

Psoriasis

Ankylosing spondylitis

Population studied

Short description of the study population

Pregnant women with diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA) or ankylosing spondyloarthritis (AS); for the etanercept treated cohort women who had any treatment with etanercept within 3 months prior to the first day of the last menstrual period (LMP) or any time during pregnancy were included.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

1300000

Study design details

Outcomes

Major congenital malformations, Any congenital malformation, preterm birth, small for gestational age, infant infections

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Data analysis plan

All birth in Sweden, Denmark and Finland between July 2006 and 2013 will be included. Birth outcomes for infants born to women with etanercept treatment will be compared to those without.

Documents

Study results

Final report for PASS study B1801396 version 3.0 final.pdf (1.65 MB)

Study report

Appendix Final report for Etanercept PASS study B1801396_ version 3.0_Final.pdf (2.22 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown